REMARKS

Claims 11-28 were pending. Claims 11, 15, 20 and 25 are amended and claims 12-14, 19, 23 and 24 are cancelled without prejudice. A Request for Continued Examination ("RCE") is concurrently filed herewith. Upon entry of these amendments, claims 11, 15-18, 20-22, and 25 to 28 will be under examination.

Support for the amendments to claim 11 can be found in claim 19 and page 6, line 11 of the specification. The amendments to claims 15, 20 and 25 involved changing the dependency of these claims and do not introduce any new matter. Therefore entry of this Amendment is respectfully requested:

Objection under 35 U.S.C. §102(b)

Claims 11, 22 and 26 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Steigerwaldt et al.

Claim 11 is amended to recite that the bee venom is intradermally administered in the range of about 0.01 mg and 1.0 mg per injection and at least one anesthetic is intradermally administered in an amount of 0.3 mg or less per injection. The Steigerwaldt reference does not teach intradermal injection of bee venom and anesthetic either simultaneously or consecutively. Further, the Steigerwaldt reference also does not teach the use of a small amount of anesthetic, i.e., 0.3 mg or less per injection to relieve acute pain and discomfort associated with bee venom injection. Therefore the Steigerwaldt reference does not anticipate claim 11, as amended, because it does not disclose each and every element of the amended claim 11.

The Steigerwaldt reference also does not anticipate claims 22 and 26 as these two claims are dependent upon claim 11 and incorporate all the claim elements of claim 11. Accordingly, reconsideration and withdrawal of the rejection is respectively requested.

Claim rejection under 35 U.S.C. §103(a)

Claims 11, 22, 26 and 27 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kim et al. in view of Ogram et al. (U.S. Patent 6,029,863).

Applicant respectfully disagrees with this rejection. These two references, either individually or in combination, do not teach or suggest that bee venom and anesthetic can be intradermally injected either simultaneously or consecutively. Nor does these references teach or

suggest that using a small amount of anesthetic, i.e., 0.3 mg or less per injection to treat acute pain caused by the injection of the bee venom.

Moreover, the present invention has achieved unexpected results. The November 9, 2000 declaration provided evidence of using "as little as 0.1 mg to about 0.3 mg per injection to provide optimal results based on injection of an equal amount of the venom by weight," and that "despite relatively little amount of local anesthetic use, a significant reduction in the pain associated with the bee venom treatment was realized by the patient." Unexpected result is also shown on page 12, lines 18-23 of the specification that "it is also unexpectedly found that one could reduce the relative amount of anesthetic introduced to levels far below those generally used in topical and local application (i.e., 1% and below) resulting in both a significant reduction and irritation associated with the injection of the bee venom and, at the same time, the elimination of the irritation associated with the intradermal administration of the anesthetic." These unexpected results further support Applicant's contention that claims 11, 22, 26 and 27, as amended, are non-obvious over the cited prior art references.

With respect to the rejection assertions that "arguments of counsel cannot take the place of evidence in the record", applicant respectively points out that the Office Action erred on facts as the November 9, 2000 declaration and the specification are proper evidence in the record to support the undersigned's argument that all pending claims are non-obvious over cited prior art references. Therefore, claims 11, 22, 26 and 27 are non-obvious over the cited two references. Accordingly, reconsideration and withdrawal of the rejection is respectively requested.

CONCLUSION

In view of the claimed amendments and the remarks, this application is believed to be in condition for allowance. Therefore, the issuance of a Notice of Allowance is earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

No fee is deemed necessary in connection with the filing of this amendment as the final Office Action was issued on July 12, 2001 and this Amendment is filed within three months of the final Office Action. If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 11, 2001

Respectfully submitted,

By lance liu

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MARKED-UP COPY OF AMENDED CLAIMS:

11. (Amended) A method of administering bee venom to a patient in need of such treatment comprising the steps of:

administering to a patient, simultaneously or consecutively, ~~both~~ (1) between about 0.01 mg and about 1.0 mg per injection ~~a therapeutically effective amount~~ of bee venom intradermally, subcutaneously or intramuscularly and (2) at least one anesthetic in an amount of 0.3mg or less per injection, intradermally, subcutaneously or intramuscularly, wherein the administration of said anesthetic ~~being provided in an amount which is sufficient to reduce~~ reduces the irritation associated with the injection of ~~said therapeutically effective amount of~~ said bee venom.

15. (Amended) The method of claims 11~~, 12, 13 or 14~~ further comprising at least one excipient or liquid carrier in which at least one of said bee venom and said anesthetic are mixed, dissolved or suspended.

20. (Three Times Amended) The method of claim ~~19~~ 17 wherein said bee venom is administered in an amount of between about 0.05 mg and about 0.5 mg per injection.

25. (Twice Amended) The method of claim ~~24~~ 11 wherein said anesthetic is administered in an amount of about 0.1 mg to about 0.3 mg per injection.